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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|---------------------------|----------------------|---------------------|------------------|
| 09/813,119 | 03/19/2001 | Michael J. O'Connor | MICRU: 56212 | 2506 |
| 24201 | 7590 12/24 | /2003 | EXAM | IINER |
| | R PATTON LEE | FARAH, A | FARAH, AHMED M | |
| HOWARD F | IUGHES CENTER ER DRIVE | | ART UNIT | PAPER NUMBER |
| TENTH FLOOR | | | 3739 | ····· |
| LOS ANGEI | LES, CA 90045 | | | _ |

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/813,119

Applicant(s)

O'Connoor et al.

Examiner

Ahmed M. Farah

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| The MAILING DATE of this communication appears of | n the cover sheet with the correspondence address | | | |
|--|--|--|--|--|
| Period for Reply | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the | | | | |
| mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply within the If NO period for reply is specified above, the maximum statutory period will apply at Failure to reply within the set or extended period for reply will, by statute, cause the Any reply received by the Office later than three months after the mailing date of the earned patent term adjustment. See 37 CFR 1.704(b). | nd will expire SIX (6) MONTHS from the mailing date of this communication. a application to become ABANDONED (35 U.S.C. § 133). | | | |
| Status | | | | |
| 1) X Responsive to communication(s) filed on Aug 18, 2 | 003 | | | |
| 2a) ☐ This action is FINAL . 2b) ☒ This acti | on is non-final. | | | |
| Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213. | | | | |
| Disposition of Claims | | | | |
| 4) 💢 Claim(s) <u>1-23</u> | is/are pending in the application. | | | |
| 4a) Of the above, claim(s) | is/are withdrawn from consideration. | | | |
| 5) | is/are allowed. | | | |
| 6) 💢 Claim(s) <u>1-23</u> | is/are rejected. | | | |
| 7) | is/are objected to. | | | |
| 8) | are subject to restriction and/or election requirement. | | | |
| Application Papers | | | | |
| 9) \square The specification is objected to by the Examiner. | | | | |
| 10) ☐ The drawing(s) filed on is/are a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | |
| 11) The proposed drawing correction filed on | is: a) \square approved b) \square disapproved by the Examiner. | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | |
| 12) The oath or declaration is objected to by the Exami | ner. | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | |
| 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | |
| a) All b) Some* c) None of: | | | | |
| 1. Certified copies of the priority documents have been received. | | | | |
| 2. Certified copies of the priority documents have been received in Application No. | | | | |
| application from the International Bure | | | | |
| *See the attached detailed Office action for a list of th | | | | |
| 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). | | | | |
| a) The translation of the foreign language provisional application has been received. | | | | |
| 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) | 4) Interview Summary (PTO-413) Paper No(s). | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) Notice of Informal Patent Application (PTO-152) | | | |
| 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). | 6) Other: | | | |

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 2. Claims 1-3, 5-10, 12-14, 16-21 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Nelson et al. U.S. Pat. No. 6,063,080.

As to claims 1-3, 6, 8, 12-14 and 17, Nelson et al. disclose a variable stiffness heating catheter 12 for use in interventional vascular therapy, comprising:

a heating catheter shaft (hollow shaft 50; see Fig. 5) having a proximal end and a distal end 14, said heating catheter shaft including at least one electrically conductive element (tabular electrode 18 and/or guide wire 80); and

reinforcing tubes (coaxial tubes 40, 52, 54 and electrode 18; see Fig. 5 and Col. 6, lines 1-34) attached to the heating catheter shaft (hallow shaft 50 which incloses RF electrode 18 and guide wire 80), the heating catheter shaft extending through the reinforcing tubes (heating

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electrode 18 and guide wire 80, which extend through hollow tubes 40, 52 and 54), wherein at least one of said reinforcing tubes has a surface defining a plurality of apertures (micro-apertures 84) to provide variation in stiffness along the length of the heating catheter shaft (see Fig. 4 and Col. 7, lines 49-52).

As to the functional limitation "electrically conductive member providing resistive heating in claims 1 and 13," the examiner's position is that the RF electrode 18 would inherently generate resistive heating. This is due to the fact that all electrically conductive metals, except very specialized/unique alloys, show certain degrees of resistivity against applied electrical currents. The degree of resistance depends the type/material of the conductor and its temperature. Hence, as electric current follows through a conductor, its resistance against the applied current generates resistive heating, which is dissipated into the surrounding area..

As to claims 5, 7, 16 and 18, the outer surface of at least one of the reinforcing tube (coaxial tube 40) has a configuration selected from the set consisting of: a continuous tube having a constant diameter, a continuous tube having a continually tapered diameter, a continuous tube having at least a portion of which has a tapered diameter, a series of tubes of varying degrees of flexibility which are fixed connected together in a coaxial, end-to-end manner," and any combination thereof. See Col. 6, lines 10-28.

As to claims 9 and 20, the outer tube of their catheter is constructed of a nylon (Merriam Webster's Collegiate Dictionary defines nylon as any of a family of high-strength, resilient synthetic polymers, the molecules of which contain the recurring amide group CONH). See

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Col.4, lines 59-62.

As to claims 10 and 21, Fig. 3 of Nelson et al. clearly shows that the catheter body 12 is sealed by pressure fit or heat shrinking (Col. 6, lines 63-67).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 4 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. in view of Mueller U.S. Pat. No. 4,801,297.

Although Nelson et al., described above, form lateral slits (micro-apertures 84) on the outer surface of their catheter to increase its flexibility, they fail to teach the use of helical slits as presently claimed.

However, Mueller teaches a flexible medical catheter 10 having a plurality of axial slits 20 and a plurality of helical slits 28 disposed on the outer surface of the catheter body 12 so as to increase the flexibility of the catheter tip 24 (Fig. 1; Col. 1, lines 64-67; and Col. 2, lines 15-20). The increase in flexibility enables the catheter to bend very easily within a body lumen thereby reducing the risk of arterial wall puncture and damage.

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Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Nelson et al. with Mueller and form helical and/or axial slits on the outer surface of the catheter body in order to increase its flexibility. Since these are not critical, provide no unexpected results, the helical and/or axial slits would have been an equivalent alternative pressure release to the lateral slits of Nelson et al.

4. Claims 11 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. in view of Nardella U.S. Pat. No. 5,334,193.

Although Nelson et al., described above, teach that the outer body of their catheter is made of polymer (nylon), their polymer is not selected from the group consisting of polyethylene, polytetrafluoroethylene, polyetherethulketone or polyphenylenesulfide as presently claimed.

However, Nardella discloses an electrosurgical catheter manufactured of flexible, biocompatible polymer, such as polyolefins, nylons, or polytetrafluoroethylene. He further teaches that the use, compatibility, and/or interchangeability of the different polymers are well known in the art of manufacturing medical catheters (Col. 5, lines 12-21). Thus, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Nelson et al. in view of Nardella to have a catheter body manufactured of polytetrafluoroethylene polymer. Furthermore, it is known in the art that the flexible polymeric materials such, polyethylene, polyvinylcholoride, or polytetrafluoroethylene behave as heat resistant when an electric potential is applied across them.

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Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. Farah whose telephone number is (703) 305-5787. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak, can be reached on (703) 308-0994. The official fax number for the group is (703) 872-9302; the fax number for After Final is (703) 872-9303; and the Examiner's Desk-top fax is (703) 746-3368.

A. M. Farah

Patent Examiner (Art Unit 3739)

December 15, 2003

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